K113004
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DEC 2 0 2011

510(k) Summary

Applicant:	Ethicon Inc. P.O. Box 151 Route 22 West Somerville, NJ 08876 USA Phone: +1-918-218-2457 Fax: +1-9918-218-2595
Date:	October 6, 2011
Contact Person:	Peter Cecchini
Proprietary Device Name:	PDS™ Barbed Sutures
Common Device Name:	Suture, Surgical, Absorbable, Polydioxanone
Classification:	Absorbable Polydioxanone Surgical Suture, Class II, 21 CFR 878.4840, Product Code: NEW
Predicate Devices:	PDS II™ (polydioxanone) Suture (N18331) PDS™ Plus Antibacterial (polydioxanone) Suture (K061037) Quill™ Self-Retaining System (SRS) (K080985)
Manufacturer:	Ethicon Inc. P.O. Box 151 Route 22 West Somerville, NJ 08876 USA

Substantially Equivalent To:

PDS Barbed sutures are substantially equivalent to the following devices:

PDS II (polydioxanone) Suture (N18331)
PDS Plus Antibacterial (polydioxanone) Suture (K061037)
Quill™ Self-Retaining System (SRS) (K080985)

The V-Loc™ 180 device (K091087) is being referenced as a device with unidirectional barbs. Therefore, the technology of unidirectional barbs is not new.

Description of the Device Subject to Premarket Notification:

PDS Barbed Sutures (polydioxanone) monofilament synthetic absorbable sutures are prepared from the polyester, poly (p-dioxanone). The empirical molecular formula of the polymer is $(C_4H_6O_3)_x$. PDS Barbed Sutures will be available marketed with and without IRGACARE®‡ MP (triclosan), a broad spectrum antibacterial agent, at no more than 2360 ug /m. PDS Barbed Sutures are dyed with D&C Violet No. 2 (21CFR§ 74.3602). PDS Barbed Sutures consists of an absorbable monofilament strand thread with unidirectional barbs, with a surgical needle attached at one end and a fixation tab at the other. The barbs and fixation tab design allow for tissue approximation without the need to tie surgical knots.

Indications for Use:

PDS Barbed Sutures are indicated for general soft tissue approximation where use of an absorbable suture is appropriate.

Performance Data:

Non-clinical laboratory testing was performed demonstrating that the device conforms to the current USP Monograph for absorbable surgical sutures, except for diameter. In addition, bench, human cadaver and animal testing was provided showing that the device performed as intended and as claimed.

Summary of Technological Characteristics of the New Device to Predicate Devices:

The new device has similar technological characteristics as the predicate devices. Like the currently marketed devices, PDS Barbed Suture is a sterile, monofilament synthetic absorbable suture intended for the approximation of soft tissue that conforms to the USP Monograph for absorbable surgical sutures, except for diameter. Similar to the currently marketed PDS Plus suture, PDS Barbed Suture will also be available as a suture product with IRGACARE ®‡ MP, an antibacterial agent.

Conclusions:

PDS Barbed Sutures have the same intended use and similar indications for use as the predicate devices. The technological differences between PDS Barbed Sutures and the predicate devices raise no new questions of safety or effectiveness. PDS Barbed Sutures met all testing criteria to demonstrate substantial equivalence to the predicates devices.

* *Trademark*
IRGACARE®‡ MP (triclosan) "Registered Trademark of BASF Group"

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC 2 0 2011

Ethicon, Inc.
% Mr. Peter Cecchini
P.O. Box 151
Route 22 West
Somerville, New Jersey 08876

Re: K113004
Trade/Device Name: PDS™ Barbed Sutures
Regulation Number: 21 CFR 878.4840
Regulation Name: Absorbable polydioxanone surgical suture
Regulatory Class: Class II
Product Code: NEW
Dated: October 06, 2011
Received: October 07, 2011

Dear Mr. Cecchini:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) No (if known): K113004

Device Name: PDS™ Barbed Sutures

Indications for Use:

PDS Barbed Sutures are indicated for general soft tissue approximation where use of an absorbable suture is appropriate.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

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